



Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	1	Attorney Docket Number	50657-00004USPT
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Complete if Known

Application Number	10/820,656
Filing Date	April 8, 2004
First Named Inventor	Robert G. Schaub
Art Unit	N/A
Examiner Name	Not Yet Assigned

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	1	WO 01/32144 A1	05-10-2001	Inhale Therapeutic Systems, Inc.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	2	Russell, K.E., et al., Intratracheal Administration of Recombinant Human Factor IX (BeneFix™) Achieves Therapeutic Levels in Hemophilia B Dogs., Thromb Haemost 2001; 85: 445-9.	

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Examiner Signature		Date Considered	2/12/06
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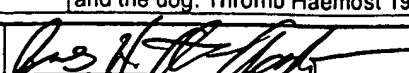
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		Number-Kind Code ² (if known)			
QUAA	AA	US-6,518,239	02-11-2003	Mei-Chang Kuo	
QUAA	AB	US-6,372,258	04-16-2002	ROBERT M. PLATZ	

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QUAA	CA	Liles D, et al., Extravascular administration of Factor IX: Potential for replacement therapy of canine and human hemophilia B. Thromb Haemost 1997; 77: 944-8.	
	CB	Patton JS, Platz RM. Pulmonary delivery of peptides and proteins for systemic action. Adv Drug Del Rev 1992; 8: 179-96.	
	CC	Hubbard RC, et al., Fate of aerosolized recombinant DNA-produced alpha1-antitrypsin: Use of epithelial surface of the lower respiratory tract to administer proteins of therapeutic importance. Proc Natl Acad Sci 1989; 86: 680-4.	
	CD	Brinkhous KM, et al., Recombinant human Factor IX: Replacement therapy, prophylaxis, pharmacokinetics, and immunogenicity in canine hemophilia B. Blood 1996; 88: 603-10.	
	CE	Russel KE, et al., Intratracheal administration of recombinant human Factor IX (BeneF.IX™) achieves therapeutic levels. Blood 1998; 92: 356a.	
	CF	Evans JP, et al., Canine Hemophilia B resulting from a point mutation with unusual consequences. Proc Natl Acad Sci USA 1989; 86: 10095-9.	
	CG	Kay MA, et al., In vivo gene therapy of hemophilia B: Sustained partial correction in Factor IX-deficient dogs. Science 1993; 262: 117-9.	
	CH	Herzog R, et al., Absence of circulating Factor IX antigen in hemophilia B dogs of the UNC Chapel Hill Colony. Thromb Haemost 2000; 84: 352-4.	
	CI	Harrison S, et al., Development of a serum-free process for recombinant Factor IX expression in Chinese hamster ovary cells. Thromb Haemost 1995; 73: 1222.	
	CJ	Foster WB, et al., Development of a process for purification of recombinant human Factor IX. Blood 1995; 86: 870a.	
	CK	Rodrigues H, et al., Analytical characterization of recombinant human Factor IX: Pharmacokinetic studies in the rat and the dog. Thromb Haemost 1995; 73: 1206.	
QUAA	CL	Keith JC, et al., Evaluation of recombinant human Factor IX: Pharmacokinetic studies in the rat and the dog. Thromb Haemost 1994; 73: 101-5.	
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CM	Lee RI, White PD. A clinical study of the coagulation time of blood. Am J Med Sci 1913; 145: 495-503.
CN	Brinkhous KM, et al., Evaluation of sensitivity of whole blood clotting time (WBCT), partial thromboplastin time (PTT), and F.IX one-stage bioassay tests with low plasma F.IX levels observed with transfusion or gene therapy in canine hemophilia B. Blood 1993; 82 (Suppl 1): 592a.
CO	Mustafa RL, et al., A role for whole blood clotting time as a sensitive screening test for F.VIII and F.IX replacement. Blood 1998; 92: 96b.
CP	Pedersen PV. Novel Deconvolution Method for Linear Pharmacokinetic Systems with Polyexponential Impulse Response. J Pharm Sci 1980; 69:312-8.
CQ	Gerrard AJ, et al., Subcutaneous injection of Factor IX for the treatment of haemophilia B. British Journal of Haematology 1992; 81: 610-3.
CR	McCarthy KP, et al., Subcutaneous bioavailability of recombinant Factor IX (BeneF.IX™) in healthy beagle dogs and cynomolgus monkeys. Blood 1996; 88: 68b.
CS	Cheung WF, et al., Identification of the endothelial cell binding site for Factor IX. Proc Natl Acad Sci USA 1996; 93: 11068-73.
CT	Wolberg AS, et al., Human Factor IX binds to specific sites on the collagenous domain of collagen IV. J Biol Chem 1997; 272: 16717-20.
CU	Brinkhous KM, et al., Subcutaneous recombinant Factor IX (BeneF.IX™) administration produces therapeutic levels of F.IX activity in hemophilia B dogs. Blood 1996; 88: 422a.
CV	Yu J, Chien YW. Pulmonary drug delivery: Physiologic and mechanistic aspects. Crit Rev Therap Drug Carr Sys 1997; 14: 395-453.
CW	Brain JD, et al., Pulmonary distribution of particles given by intratracheal instillation or by aerosol inhalation. Environ Res 1976; 11: 13-33.
CX	Colthorpe P, et al., The pharmacokinetics of pulmonary-delivered insulin: A comparison of intratracheal and aerosol administration to the rabbit. Pharm Res 1992; 9: 764-8.
CY	Gillespie MN, et al., Pulmonary metabolism of exogenous enkephalins in isolated perfused rat lungs. J Pharmacol Exp Ther 1985; 232: 675-8.
CZ	Jendle J, et al., Delivery and retention of an insulin aerosol produced by a new jet nebulizer. J Aerosol Med 1995; 8: 243-54.
CA1	Jendle JH, et al., An exploration of intrapulmonary insulin administration in anaesthetized and mechanically ventilated pigs. Scand J Clin Lab Invest 1996; 56: 251-8.
CB1	Laube BL, et al., Preliminary study of the efficacy of insulin aerosol delivered by oral inhalation in diabetic patients. JAMA 1993; 269: 2106-9.
CC1	Gupta S, et al., Pulmonary delivery of human protein C and Factor IX, in (ed) NaL (ed): Oxygen Transport to Tissue XVIII. New York: Plenum Press 1997; p 429-35.
CD1	Wigley FM, et al., Insulin across respiratory mucosae by aerosol delivery. Diabetes 1971; 20: 552-6.
CE1	Lusher JM. Thrombogenicity associated with Factor IX complex concentrates. Semin Hematol. 1991;28(3 supp.6):3-5.
CF1	Shapiro AD, Ragni MV, Lusher JM, et al. Safety and efficacy of monoclonal antibody purified IX concentrates in previously untreated patients with hemophilia B. Thromb Haemost. 1996;75(1):30-35.
CG1	Roberts HR, Eberst ME. Current management of hemophilia B. Hemat Oncol Clin North Am. 1993;7(6):1269-1280.
CH1	Kasper CK, et al. A more uniform measurement of factor VIII inhibitors. Thromb Diathes Haemorrh 34:869-872, 1975.
CI1	Giles AR, A detailed comparison of the performance of the Standard versus Nijmegen modifications of the Bethesda Assay in detecting factor VIII. Thromb. Haemost 79:872-5,

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